

PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen



SE00/1278

REC'D 04 SEP 2000	SEARCHED	INDEXED
SERIALIZED	FILED	PCT

4
Intyg
Certificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

(71) Sökande SHL Medical AB, Nacka SE
Applicant (s)

(21) Patentansökningsnummer 0000732-8
Patent application number

(86) Ingivningsdatum 2000-03-06
Date of filing

Stockholm, 2000-08-14

För Patent- och registreringsverket
For the Patent- and Registration Office

A. Södervall
Anita Södervall

Avgift
Fee

**PRIORITY
DOCUMENT**
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

BEST AVAILABLE COPY

DEVICE FOR AN INHALER

TECHNICAL FIELD

The present invention relates to a device for an inhaler, which inhaler
5 comprises an inhalation opening, a container containing medicament,
an actuating means capable of delivering a dose of medicament from
the container, a movement means connected to the actuating means
and arranged such in the inhaler that it is moved by inhalation
through the inhalation opening.

10

BACKGROUND OF THE INVENTION

Many inhalers for medicament on the market are equipped with so
called breath-activated devices. These often include some actuating
means that, in response to a pressure drop and/or air flow through
15 the inhaler and the inhalation opening, activates a mechanism that
delivers a dose of medicament from a medicament container. The
main object with the breath-activation is to facilitate for the patient to
obtain a dose of medicament, in comparison to the manually
operated inhalers where the patient needs to activate the delivery by
20 hand and inhale at the same time. This coordination of actions from
the patient often causes problems so that, if the patient do not
coordinate properly, the patient may not receive an adequate dose of
medicament.

- 25 In the case of aerosol-driven inhalers the breath-activation causes a
spring to compress a canister containing the medicament and
propellant so that the medicament is delivered. Either a metered dose
is delivered or the canister is open a predetermined time under which
time medicament is delivered continuously. In the case of powder
30 inhalers, the breath activation causes access to an amount of powder
to be inhaled or a dose to be delivered. Other types of inhalers, such

as nebulizers, may also have breath-activated devices for activating the delivery of a dose, or quantity, of medicament.

- Some of the breath-activated devices comprise some form of plate-shaped lid, flap or vane movably arranged in an air flow path in the inhaler or adjacent an air intake. Upon inhalation the pressure drop and/or air flow causes the plate to move and thereby activate the actuating means so that a dose is delivered.
- 10 Some of the breath-activated inhalers are also arranged with return means. These return means "reset" the actuating means to a ready state so that the inhaler is ready for use for the subsequent inhalation. The return means also recharge the inhaler, e g refills a metered dose chamber with medicament for subsequent use. The 15 return means are either operated manually, e g when a protective cover is closed or opened, or automatically, either at a specific time after inhalation or when the inhalation is terminated.

- A drawback with the above described devices is that the breath-activated devices may unintentionally be triggered when the inhaler is ready for inhalation if the inhaler is dropped or otherwise exposed to sudden forces. Since the plates, vanes or flaps should be able to move by rather small forces exerted by the pressure drop/air flow during inhalation, they might also rather easily be moved by a sudden movement or sudden change of movement of the inhaler, such as if the inhaler is shaken or hits an object when it is ready for inhalation.

- 20 A number of doses important to the patient could be lost in this way. Further, the doses will, for many types of inhalers, be delivered inside the inhaler if triggered unintentionally. The medicament delivered 30 inside the inhaler may deposit in passage ways or mechanisms of the inhaler and possibly obstruct the function or rendering the inhaler

unclean. The deposition may also affect the dose-to-dose equivalence in that a lesser amount of medicament is inhaled than intended, and in that the deposited medicament may break loose during inhalation, whereby the amount is larger than intended.

5

- In context with inhalers with automatic recharging means, an unintended triggering of the inhaler may also lead to an improper filling of the metered dose chamber if for example the inhaler is held in such a position during recharging that the medicament cannot 10 properly fill the chamber. This could for example be the case with aerosol driven canisters that have to be held in a substantially vertical position when refilling the metered dose chamber, in particular when the canister is not full. The improper filling of the metered dose chamber leads to an improper dose delivered to the 15 patient at the subsequent inhalation.

BRIEF DESCRIPTION OF THE INVENTION

It is an object of the present invention to remedy the above mentioned problems and to provide a device for the above mentioned type of 20 inhalers which reduces the risk of unintentional triggering of the inhaler.

- This object is obtained according to one aspect of the invention characterised in that the movement means comprises at least one 25 pivotably arranged member, whereby the member, or members, is balanced such around its pivoting point that forces acting on the member(-s) during sudden changes in movement of the inhaler do not affect the member(-s) so that a dose is delivered.
- 30 According to a further aspect of the invention it is characterised in that the movement means comprises a balancing means arranged such to the member(-s) that the forces acting on the member(-s)

during sudden changes in movement of the inhaler are balanced out by the balancing means.

According to yet another aspect of the invention, it is characterised in
5 that the moment of the balancing means is substantially the same as
the moment of the member(-s).

With a device according to the invention, the movement means, such
as for example a plate or a flap, or a member of the movement means,
10 such as a pivotally arranged linkage, or combinations of several
pivotably arranged members, is held substantially stationary when
the inhaler is subjected to sudden movements, but is activated, or
moved, during inhalation. This prevents unintentional activation of
the inhaler because of forces acting on, and trying to pivot, a member
15 of the movement means.

Preferably the member of the movement means is balanced as
regards to forces exerted on the inhaler so that the point of
momentum of the member is arranged at or near its pivoting axis.
20 This will prevent the member from being pivoted because of
acceleration or retardation. With a device according to the invention,
external forces on the inhaler will not trigger the breath-activated
device as easily as with known inhalers of this type when the inhaler
is in a ready-to-use state.

25 In one embodiment, when the member of the movement means is
designed as a pivotable plate-like flap, a balancing means which has
a moment substantially equal to the moment of the flap is arranged
on the opposite side of the pivoting point. The balancing means then
30 balances the flap so that it is held stationary when the inhaler is
subject to external forces in a very simple but yet effective way

These and other aspects of and advantages with the invention will become apparent from the following detailed description of an embodiment and from the accompanying drawings.

5 **BRIEF DESCRIPTION OF THE DRAWINGS**

In the detailed description of the invention, reference will be made to the accompanying drawings, of which

Fig. 1 shows a side view in cross-section of an inhaler
10 comprising the present invention,

Fig. 2 shows a detailed perspective view, partly cut away, of a breath-activated component according to the invention balanced in two axes and comprised in the inhaler of Fig. 1,

15 Fig. 3 shows the component of Fig. 2 from the side,

Fig. 4 shows a detailed perspective view of a flap comprised in an inhaler, balanced in one axis,

20 Fig. 5 shows a plan view of the flap of Fig. 4,

Fig. 6 shows a side view of the flap of Fig. 4,

25 Fig. 7 shows a detailed view of another use of the present invention, and

Fig. 8 shows a detailed view of a further use of the present invention.

30 **DETAILED DESCRIPTION OF THE INVENTION**

- Figure 1 shows an example of an inhaler comprising the present invention. The inhaler 100 shown is intended for aerosol-driven medicament contained in a canister 102 arranged inside the housing 104 of the inhaler. A stem 106 of the canister is seated in a nozzle 108 provided with an outlet directed toward an inhalation mouthpiece 110. Pressure means 112 is arranged in contact with the top of the canister as seen in the figure. The pressure means comprises a piston 114 and a pressure plate 116. Compression springs 118 are arranged between the pressure plate and the housing. Actuating means 120 are arranged in connection with the pressure plate for holding it in a position where the compression springs are tensioned. The actuating means further comprise levers and shuttles.
- Fig. 2 shows a detail of a component 10 of a breath- activated inhaler. The component comprises an air intake passage 12 , through which air flows during inhalation. In the air intake a flap or vane 14 is arranged pivotably around a pivot axis 16. Spring means (not shown) urges the pivot upwards in Fig. 2 against the interior wall of the air intake. In this position the flap or vane substantially blocks the air intake passage. The part of the vane opposite the pivoting axis is connected to the actuating means 120.
- The general function of the component is that during inhalation, a pressure difference is created between the interior and the exterior of the inhaler housing 104. This pressure difference causes the flap or vane 14 to pivot around the pivoting axis 16 against its spring means so that the air intake opens and an air flow is created. The pivoting movement of the flap or vane triggers the actuating means so that the hold of the pressure plate 116 is released whereby the springs 118 depresses the canister 102. In turn the stem 106 is pushed into the

canister whereby a dose of medicament is delivered through the mouthpiece 110.

The flap or vane is arranged with balancing means 18. In the 5 embodiment shown in Figs. 1 and 2 it comprises a weight arranged on the opposite side of the pivoting point in relation to the flap or vane. The centre of mass 20 of the weight is arranged in the same plane as the centre of mass 22 of the flap or vane and the pivoting point. The weight of the balancing means is chosen such that the 10 weight times the distance to the pivoting point equals the weight of the flap or vane times the distance between its centre of weight and the pivoting point. With this arrangement the flap or vane is balanced as regards external forces exerted on the inhaler in that the resulting moment on both sides of the pivoting point is the same. Since the 15 centres of mass are placed in the same plane as the pivoting point the flap or vane will be balanced for external forces in all directions.

Figs. 3-5 shows an embodiment where the flap or vane 14 is not balanced in all directions. Here the weight 18 is placed somewhat 20 below the pivoting point and the flap or vane. Here the centres of mass 22 of the flap or vane and the balancing means 20 and the pivoting point 16 will not be arranged in the same plane. Here the flap or vane will be substantially balanced along the line 26 intersecting the pivoting point and the resulting centre of mass.

25 This configuration may be due to the limited space available in the inhaler. The resulting centre of mass 24 will thus not coincide with the pivoting point of the flap or vane but with the line 26. It is however arranged such that the flap or vane is balanced for forces 30 exerted on the inhaler in selected directions. For example with an aerosol inhaler it is recommended that it is shaken before use so that the medicament inside the canister is properly suspended. Depending

on design of the inhaler, i. e. how it is held, it is shaken in certain directions. The inhaler shown in Fig. 1 will be shaken substantially in the vertical direction as shown by arrows 130. The flap or vane is then substantially balanced with respect to those directions.

5

Fig. 7 shows another use of the present invention. For many inhalers it is important that the inhalation forces are kept low, making it necessary to have the actuating means respond to these low forces. On the other hand the depression forces need to be rather high in 10 order to be capable of overcoming the forces for depressing the canister. Therefore, it is necessary with some kind of transmission mechanism which amplifies the movement from the flap or vane to the compression springs. Fig. 7 shows one example of how the first link of the transmission comprises a lever 150 pivotably arranged.

15

The lever is connected to the flap or vane 14 via a piston 152. A second arm 154 or lever is connected to the lever via a ledge 156. The transmission 158 comprises further arms, levers, pistons, shuttles and the like in order to transmit and transfer the movement to a 20 holding means 160 holding the pressure plate 116 against the force of the compression springs 118. When a patient inhales, the flap 14 is pivoted around its pivoting axis whereby the piston 152 is pushed downwards. The piston pivots the lever 150 whereby the arm 154 disconnects from the ledge. The movement is transferred through the 25 transmission until the holding means 160 releases the pressure plate. Because very small forces are needed, and desired, in order to pivot the lever, it is balanced against external forces according to the invention. A weight 162 is arranged on the opposite side of the pivoting point and chosen such that the resulting centre of mass of 30 the weight an the lever coincides with the pivoting point 164, whereby the lever is balanced against directed forces, for example vertically as seen in Fig. 7.

- Fig. 8 shows a detailed view of a locking and release means for a breath activated inhaler. It comprises a first pivoting member 212 pivotable around an axis. The first member is arranged with a surface 214 inclined with respect to a vertical axis as seen in Fig. 2. The 5 lower end of an arm 200 arranged to a breath activated member, not shown, is arranged with a mating inclined surface 216. The first member is provided with an upwards facing ledge 218, on which ledge a second pivotable member 219 rests with a recess 220, thus holding the second member in a substantially horizontal position. A 10 third member 222, arranged slidably in a vertical direction rests with a lower end on the second member. The third member is attached to a holding member, which holds for example pressure springs arranged to a canister of an inhaler in an energised, tensioned state. As soon as the arm 200 is moved downward, whereby the subsequent 15 members are brought out of contact with each other, the canister is depressed by the force of the springs. In order for the inhaler not to be activated by sudden forces, the first member 212 is balanced so that its centre of mass is placed in the pivoting point of the member.
- 20 Even though the present invention has been described in connection with an aerosol inhaler, it is to be understood that it is equally applicable to other types of inhalers such as powder and nebulisers, as well as for nasal inhalers working with the same principles.
- 25 It is to be understood that the present invention may be used for balancing statical as well as dynamical forces, i e predetermined directions of movement, non-predetermined directions of movement as well as movements in several planes.
- 30 Even though the invention has been explained in connection with a balancing means arranged to the flap and lever of the transmission mechanism, it is to be understood that the principles of the invention

may be utilised for other components of an inhaler which are pivotably arranged.

In this context it is to be understood that the wording "pivotably" may
5 be members balancing on an edge, or that the shaft on which a pivoting member is arranged is smaller than the hole, so that there is one specific contact point, pivoting point, between the shaft and the hole.

PATENT CLAIMS

1. Device for an inhaler (10), which inhaler comprises an inhalation opening, a container containing medicament, an actuating means capable of delivering a dose of medicament from the container, a
5 movement means (14) connected to the actuating means and arranged such in the inhaler that it is moved by inhalation through the inhalation opening, **c h a r a c t e r i s e d** in that the movement means comprises at least one pivotably arranged member (14), whereby the at least one member is balanced such around its
10 pivoting point (16) that forces acting on the at least one member during movement of the inhaler, causing acceleration/retardation, do not affect the at least one member.
2. Device according to claim 1, **c h a r a c t e r i s e d** in that the
15 movement means comprises a balancing means (18) arranged such to the at least one member that the forces acting on the at least one member during said movement of the inhaler are balanced out by the balancing means.
- 20 3. Device according to claim 1 or 2, **c h a r a c t e r i s e d** in that the moment of the balancing means is substantially the same as the moment of the at least one member.

ABSTRACT

The present invention relates to a device for an inhaler (10), which inhaler comprises an inhalation opening, a container containing medicament, an actuating means capable of delivering a dose of 5 medicament from the container, a movement means (14) connected to the actuating means and arranged such in the inhaler that it is moved by inhalation through the inhalation opening. The invention is characterised in that the movement means comprises at least one pivotably arranged member (14), whereby the member is balanced 10 such around its pivoting point (16) that forces acting on the member during movement of the inhaler, causing acceleration/retardation, do not affect the member.

(Fig. 2)

15

3
2
1
0
9
8

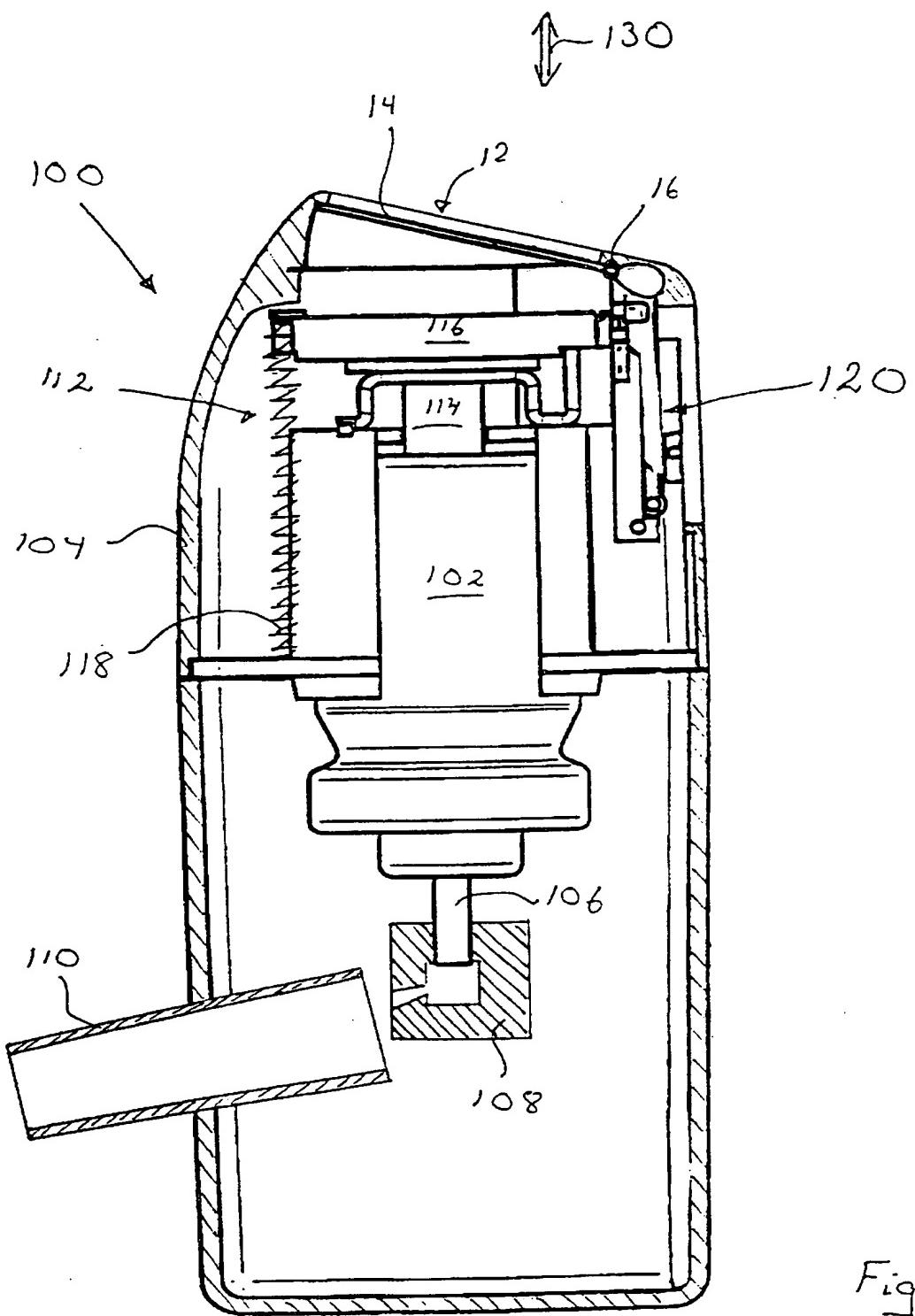


Fig. 1

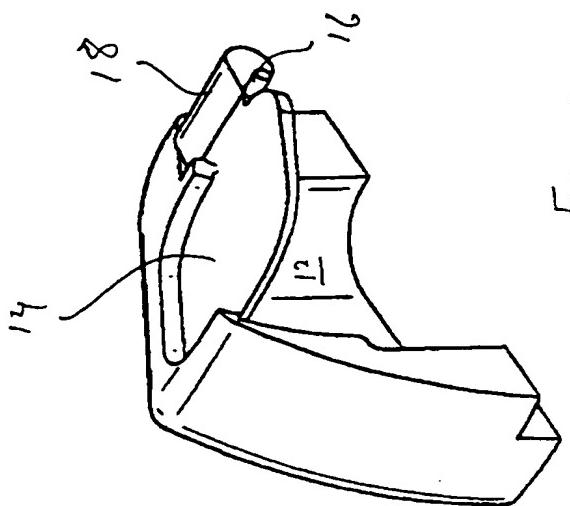


Fig. 2

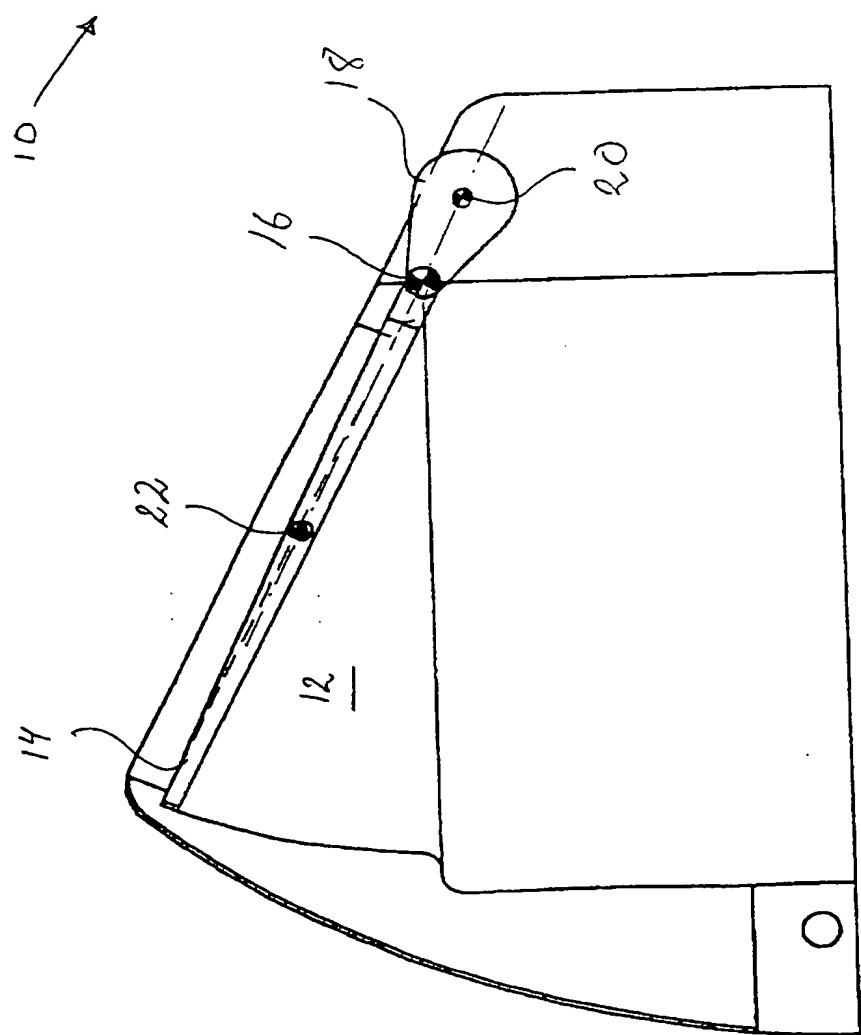


Fig. 3

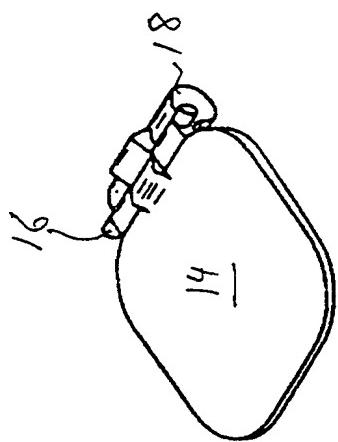


Fig. 4

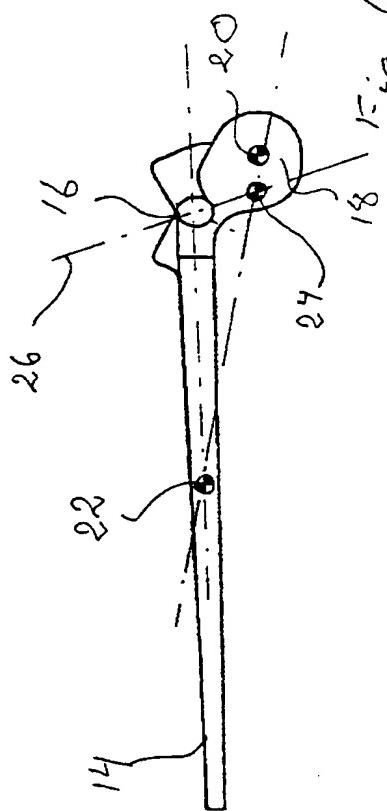


Fig. 6

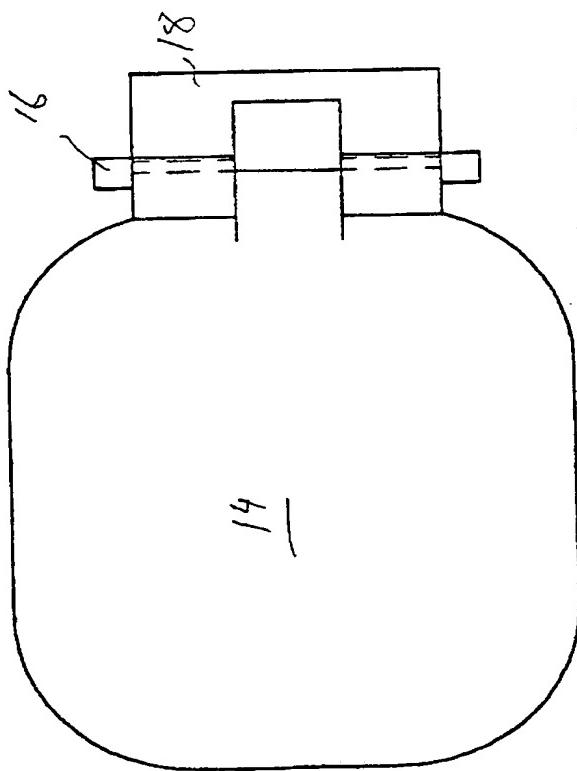


Fig. 5

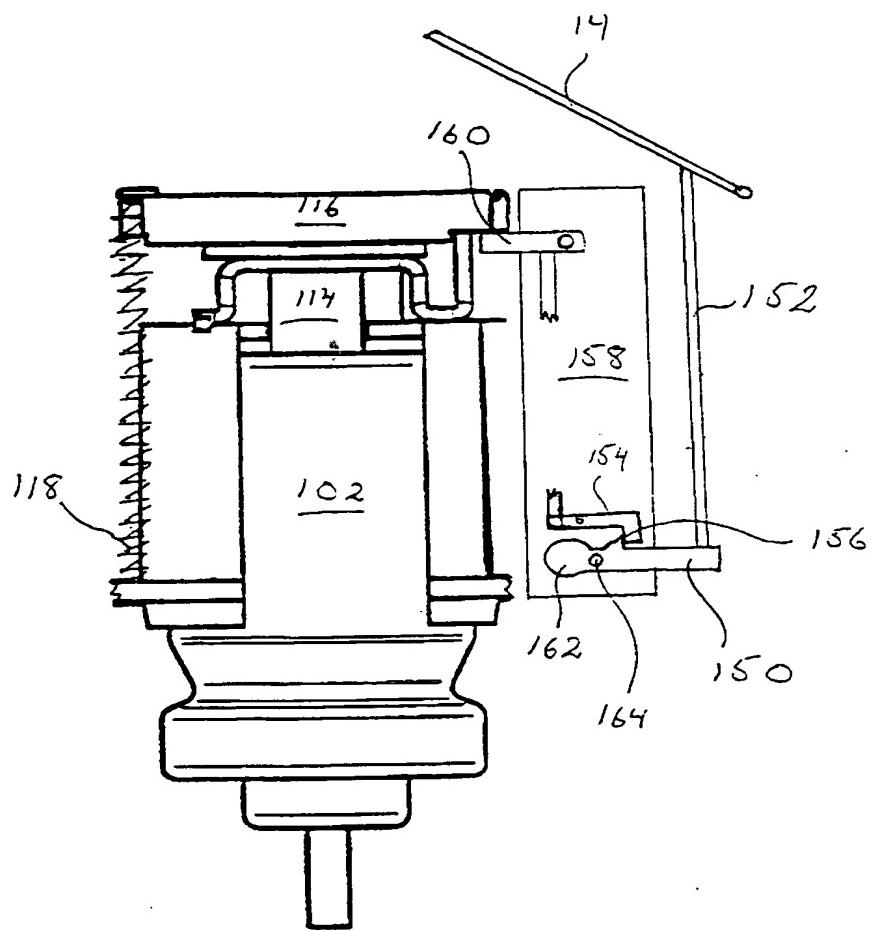


Fig. 7

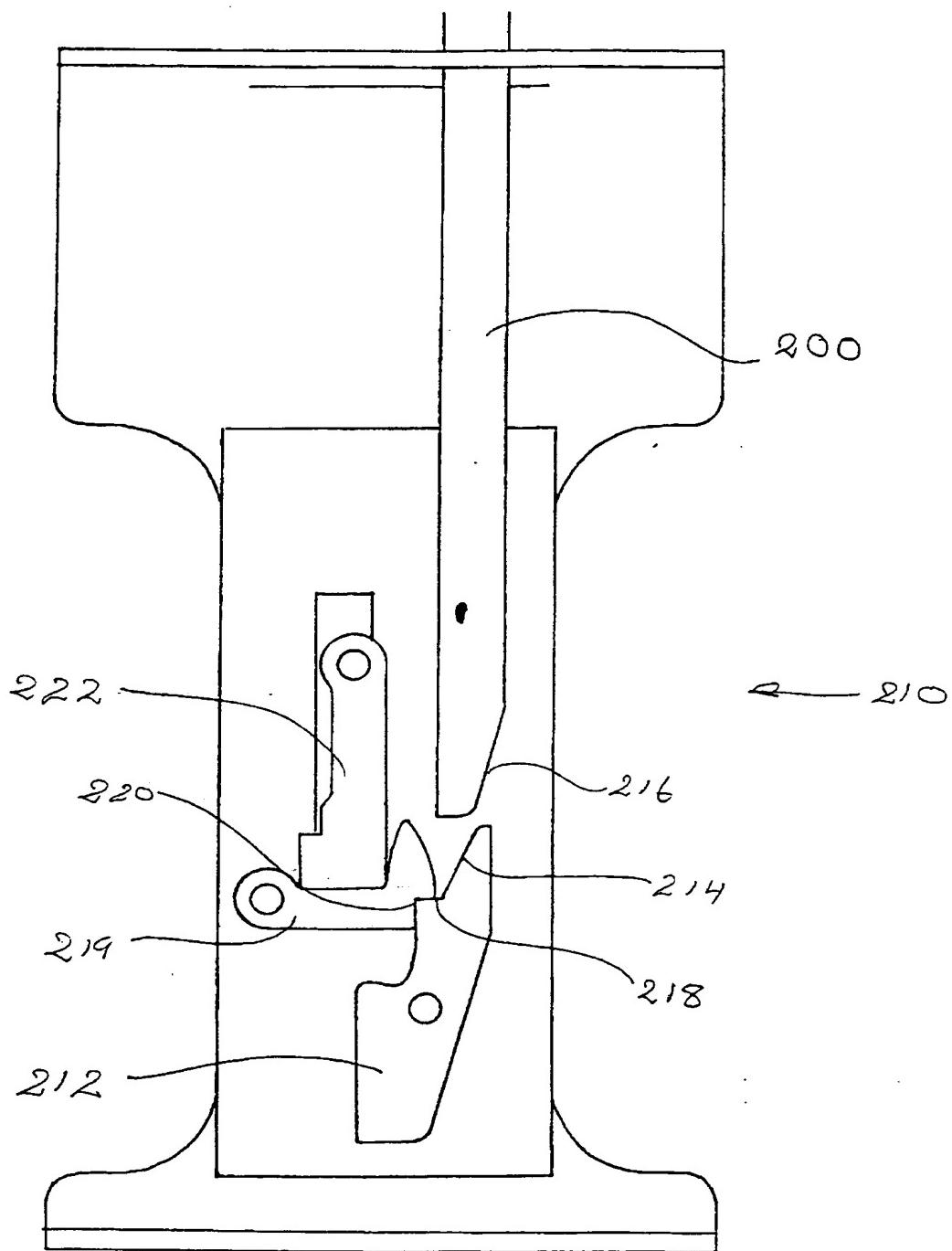


Fig. 8